Full Text OD-94-004

EXPLORATORY CENTERS FOR ALTERNATIVE MEDICINE RESEARCH

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PURPOSE

Introduction

The Office of Alternative Medicine (OAM) was mandated by Congress in 1991 and permanently established within the Office of the Director, National Institutes of Health (NIH), through the NIH Revitalization Act of 1993 (Public Law 103-43, Section 209). The mission of the OAM is to encourage and support the investigation of alternative medical (AM) practices, with the ultimate goal of integrating validated alternative medical practices into health and medical care. "AM practices" are therapies represented by preliminary clinical data on which systematic and scientific retrospective and/or prospective research projects can be based.

The AM community possesses a potentially useful accumulation of patient data that could be evaluated for treatment outcome. The NIH and OAM recognize the need for: (1) scientifically-based research for AM therapies across the range of diseases; (2) identification of the role of AM in clinical outcomes, prevention, and health improvement; (3) development of both an independent and collaborative research capacity in the AM community; (4) multi-disciplinary

research approaches in AM research;(5) a network of research organizations that includes both the AM and conventional medical communities; and, (6) dissemination of research findings.

The purpose of this RFA is to provide a mechanism to examine the potential effectiveness and validity of AM therapies and to provide clinical/scientific/technical assistance to AM investigators as they develop their research projects. The OAM encourages applications from organizations that possess a multi-disciplinary research capability involving both the AM community conventional medicine and biomedical/behavioral research investigators.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," an initiative for setting national health policy and priorities. Although "Healthy People 2000" does not currently specify an Alternative Medicine objective, this RFA involves priority areas within the "Healthy People 2000" objectives that involve alternative medical health care. Applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and not-for-profit organizations, public and private organizations such as universities, colleges, hospitals, laboratories, units of State or local governments, Federally recognized Indian Tribal organizations, and eligible agencies of the Federal government. Applications may include foreign components, but foreign organizations are not eligible to apply.

MECHANISM OF SUPPORT

The administrative and funding instrument to be used for this RFA is the Resource-Related Research Projects mechanism (U24). Under the cooperative agreement mechanism, the OAM anticipates substantial programmatic involvement with the awardee in a partner role during performance of the project. The OAM will not assume primary direction or responsibility or a dominant role in the agreement. Details of the responsibilities, relationships, and governance of the cooperative agreement are discussed under the section below entitled "Terms and Conditions

of Award." There are no plans to convert any award to a grant at the end of the initial project period.

FUNDS AVAILABLE

Approximately $1.8M in total costs (direct plus indirect) will be committed in the first year to fund up to four awards.

This funding level is dependent on the receipt of applications of high technical and scientific merit and the continued availability of funds. Because the nature and scope of applications may vary, it is anticipated that the dollar size of awards could vary.

RESEARCH OBJECTIVES

Background

The demographics, prevalence, and patterns of use of unconventional medicine in the United States have recently been described (New England J. Med. 328:246-252, 1993). The most relevant findings are the following: (a) most people use unconventional therapies for chronic rather than life-threatening medical conditions; (b) The elderly are significant users of alternative therapies; (c) users of alternative therapies do not inform their primary care physicians; (d) extrapolation to the United States population suggests that Americans made approximately 425 million visits to providers of unconventional therapy during 1990; and (e) expenditures associated with alternative therapies appear similar to non-reimbursed expenses incurred for all hospitalizations in the United States. These findings indicate that alternative medicine modalities occupy a larger role in the self-health care of U.S. citizens than previously understood.

Despite the broad use of alternative medicine treatments, there is a paucity of data available to demonstrate convincingly whether these AM practices are efficacious, safe, and/or beneficial, lead to positive clinical outcomes, improve quality of life, reduce or eliminate adverse symptoms, prevent disease, or promote or enhance health. A similar conclusion was reached in a 1990 report on unconventional cancer treatments by the U.S. Office of Technology Assessment. This report urges a systematic analysis of alternative treatments and their effect on major diseases, health, and wellness (U.S. Office of Technology Assessment, OTA-H-405, 1990, p. 225).

Exploratory Center Concept

The exploratory center is viewed as a first step in developing future specialized or comprehensive centers in Alternative Medicine. It will support planning for new interdisciplinary programs involving experienced investigators from conventional medicine and clinicians and investigators from Alternative Medicine. It will provide clinical/scientific/technical assistance to investigators, as well as funds for pilot studies on Alternative Medicine topics from investigators outside the center.

The multi- and inter-disciplinary group of research faculty should have expertise in areas such as biostatistics, computer processing, data management, protocol design, survey design, questionnaire development, basic medical laboratory evaluations, patient record data analysis, patient registries, development of databases, clinical and behavioral epidemiology and health education and health promotion.

Specific objectives for the center include:

o Establishing linkage of academic centers with Alternative Medicine investigators.

o Establishing a network of AM clinicians and investigators in specific topic areas.

o Linking investigators with common clinical interventions and data to each other and to technical expertise necessary to pursue research goals.

o Establishing an advisory committee to provide program direction and advice to the principal investigator of the center.

o Developing mechanisms for evaluating the feasibility of using data from Alternative Medicine investigators for research projects.

o Developing a mechanism for scientific/technical merit review of proposed pilot studies from investigators from outside the center's institution.

o Developing a bibliographic resource on Alternative Medicine topics.

o Developing workshops and seminars for training purposes.

o Developing plans for soliciting students to apply for Postdoctoral training in Alternative Medicine.

o Although applicants are encouraged to include population samples across the life cycle, elderly populations are particularly identified as high priority.

Centers that do not have the capability within their own institution to completely respond to this RFA may seek additional expertise from elsewhere.

Research Scope

For the purpose of this RFA, investigators must include at least three of the following six broad program areas in Alternative Medicine and demonstrate their clinical/scientific/technical expertise in their application to the evaluation of Alternative Medicine.

o Nutrition, Diet, and Lifestyle/Behavioral Health Changes.
Examples: macrobiotics, megavitamins, diets, lifestyle modification, health risk reduction/health education, wellness

o Mind/Body Control Therapies. Examples: biofeedback, relaxation, prayer therapy, guided imagery, hypnotherapy, music/sound therapy, education therapy

o Traditional and Ethnomedicine Therapies. Examples: acupuncture, ayurvedic medicine, herbal medicine, homeopathic medicine, native american medicine, natural products, and traditional oriental medicine

o Structural Manipulations and Energetic Therapies. Examples: acupressure, chiropractic medicine, massage, reflexology, rolfing, therapeutic touch, Qi Gong

o Pharmacological and Biological Therapies. Examples: anti-oxidants, cell treatment, chelation therapy, metabolic therapy, and oxidizing agents

o Bioelectromagnetic Therapies. Examples: diagnostic and therapeutic applications of electromagnetic fields (e.g., transcranial electrostimulation, neuromagnetic stimulation, electro-acupuncture).

Research Focus

Applicants should develop a multi-disciplinary research focus in one of the below listed themes, which integrates three of the six program areas above. One example could be the evaluation of

treatment outcome for Bioelectromagnetic, Mind-body, or Pharmacological and Biological therapies for certain cancers. Awards will be made in one or more of the following theme areas.

o Cancer

Investigators should determine which aspects of cancer and which three of the six program areas listed above to include.

o Pain

Investigators should include the evaluation of three of the six program areas as they pertain to acute or chronic pain. Pain related to a cancer would fit in this theme as would pain involving other diseases such as arthritis or temporomandibular disorders (jaw pain).

o Other Disease or Symptoms

Investigators may propose a research focus or theme in any other disease(s) or symptom(s) besides cancer or pain if it has a broad impact on health.

Clinical/scientific/technical Assistance Activities

Each application must demonstrate the ability to provide clinical/scientific/technical assistance to potential AM investigators and propose a plan for providing assistance to AM investigators in the chosen program areas. These activities may include, but are not limited to, the following examples of assistance:

o Choice of research methods appropriate to the AM intervention
o Development of appropriate AM protocols
o Study Design
o Methods of data collection, management, and data analysis.
o Quality control procedures
o Development of appropriate methods to assure safety of human subjects involved in research protocols
o Safety issues
o Case review methods
o Provide guidelines for applicants to use for clinical evaluation and data collection, e.g., NCI best case series.

- Develop procedures for reporting adverse effects
- Preparation for Institutional Review Board and FDA approvals.
- Preparation for Workshops, Seminars, etc. for AM investigators on relevant research topics.

One purpose of this research program is to assist AM investigators in determining whether they have adequate preliminary data to propose specific defined pilot studies or make other applications for peer-reviewed research support.

Pilot Research Project

Each Center will provide limited support to AM investigators for one-year pilot research projects. A total of up to $80,000 will be available in Year One for each Center and up to $180,000 per year in future years for each center. Each pilot project will be for a maximum of up to $7,500 for retrospective studies, e.g., data evaluation collections, etc. or up to $20,000 for prospective studies. General purpose equipment such as computers will not be supported with these funds.

The Center must propose a mechanism for solicitation of pilot research projects, application instructions, and a mechanism for scientific/technical merit review of applications, employing independent reviewers. Applications will only be accepted in the research program areas that the Center has chosen within its theme. The Center will ensure that pilot projects are funded in each of the chosen program areas.

It should be clearly understood by applicants that these pilot projects are to be specifically and solely allocated for new developmental or exploratory research in alternative medicine and not allocated to supplement any ongoing grant or other research support.

The Principal Investigator of any selected pilot project solicited by the Center must be an investigator not supported by the Center's institution or affiliates. However, individuals at the institution who are not funded by this Center award may collaborate on these pilot projects.

Allowable Expenses

Applicants should include in their budget: (a) salary for the principal investigator who should make a substantial commitment (e.g., 30%) to the center; (b) money for the support of pilot projects; (c) minimal office support; (d) advisory resources for developing collaborative resources; (e) travel for the Principal Investigator to attend and participate in at least two one-day planning/progress meetings per year in Bethesda or Rockville, MD; (f) other as needed.

SPECIAL REQUIREMENTS

Applicants should propose an appropriate structure for the center to meet the research goals and objectives stated above.

The principal investigator or Director of each funded Center will be a member of a Coordinating Committee, whose purpose is to share experiences, discuss common problems and solutions, help in the development of networks of Alternative Medicine investigators, establish common guidelines and procedures for pilot studies and, where feasible, other activities. Centers must agree to use any common guidelines and procedures agreed upon by the Coordinating Committee. It is anticipated that this Coordinating Committee will need to meet two or three times a year.

Terms and Conditions of Award

The administrative and funding instrument used for the Centers is a cooperative agreement, an "assistance" mechanism in which substantial NIH scientific and programmatic involvement with the awardee is anticipated during the performance of the agreement.

Under the cooperative agreement, the OAM purpose is to assist and stimulate each Center's planning and implementation by involvement in and working with the Centers in a partner role. The OAM role is not to assume primary direction, responsibility, or a dominant operating role in the Centers. Consistent with this concept, the primary role and total responsibility for Center programs resides with each Center. Specific tasks and activities in completing the agreement will be shared by the Center and the OAM as noted below.

These special Terms of Award are in addition to and not in lieu of applicable U. S. Office of Management and Budget administrative guidelines, HHS Grant Administration Regulations at 45 CFR Parts 74 and 92, and other HHS, PHS, and NIH Grant Administration policy statements.

1. Awardee Rights and Responsibilities

Awardees will have primary and lead responsibilities for the project as a whole, as well as collaboration with other Centers and with the OAM Project Scientist.

Awardees will retain custody of and have primary rights to the data developed under these awards, subject to Government rights of access consistent with current HHS, PHS, and NIH policies.

2. OAM Staff Responsibilities

The OAM Project Scientist will have substantial scientific and programmatic involvement in assisting the awardee in the project, participating in technical assistance activities, serving as a voting member of any individual Center's Advisory Committee, referring potential investigators to the center for technical assistance, assisting in the development of bibliographic resources in Alternative Medicine, and coordinating and involving NIH resources of clinically relevant activities outside of Alternative Medicine. OAM will convene the first meeting. The OAM Project Scientific will also serve as a voting member of the Coordinating Committee.

3. Collaborative Responsibilities

A Center Coordinating Committee, composed of the principal investigator(s) of each Center and the OAM Project Scientist, have primary responsibility for developing and implementing common procedures, guidelines, and criteria across Centers, and establishing common procedures and guidelines for pilot studies and other activities where feasible. The principal investigators and the OAM Project Scientist will have one vote each. The chairperson will be selected by the Committee and not be someone from the OAM.

Subcommittees will be established by the Coordinating Committee as appropriate; and the OAM Project Scientist will serve on subcommittees as appropriate.

The OAM Project Scientist will coordinate NIH Alternative Medicine activities with Center activities.

4. Arbitration

Any disagreement that may arise on scientific/programmatic matters within the scope of the cooperative agreement and between award recipients and the OAM may be brought to arbitration. An arbitration panel will be composed of three members: one selected by the Center Coordinating Committee, with the OAM member not voting; a second member selected by the OAM; and, the third member selected by the two prior selected members. This special arbitration procedure in no way effects the awardee's right to appeal an adverse action that is appealable in

accordance with PHS regulations at 42 CFR Part 50, Subpart D, and HHS regulation at 45 CFR Part 16.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) and supersedes and strengthens the previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minorities in Study Populations) which have been in effect since 1990. The new policy contains some new provisions that are substantially different from the 1990 policies. All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research", which have been published in the Federal Register of March 9, 1994 (FR 59 11146-11151), and reprinted in the NIH GUIDE FOR GRANTS AND CONTRACTS of March 18, 1994, Volume 23, Number 11.

Investigators may obtain copies from these sources or from the program staff or contact person listed below. Program staff may also provide additional relevant information concerning the policy.

This policy applies to the pilot studies proposed under this RFA.

LETTER OF INTENT

Prospective applicants are asked to submit, by May 9, 1994, a letter of intent that includes the number and title of this RFA; the name, address, and telephone number of the Principal Investigator(s); the identities of other key personnel and participating organizations or institutions, if any; and a title describing the proposed research.

Although a letter of intent is not required, is not binding, and does not enter into the review of applications, the information that it contains will be especially helpful to the OAM in planning for

the review of applications, estimating the potential work-load, and avoiding conflicts of interest in the review process.

The letter of intent is to be sent to Dr. John Spencer at the address listed under INQUIRIES.

APPLICATION PROCEDURES

To apply for the cooperative agreement, the research grant application form PHS 398 (rev. 9/91) is to be used. Forms are available at most institutional offices of sponsored research; from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301/435-0714; and from the OAM Project Scientist listed under INQUIRIES. Prior to writing the application, applicants should carefully read the instructions provided with the PHS 398 and this RFA.

The RFA label available in the PHS 398 application package must be affixed to the bottom of the face page of the application. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2a of the face page of the application form and the YES box must be marked.

Submit a typewritten, signed original of the application, three signed photocopies, and the completed Checklist in one package to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

At the time of submission, mail one additional complete copy of the application to:

John Spencer, Ph.D.
Office of Alternative Medicine
National Institutes of Health
6120 Executive Boulevard, Suite 450
Rockville, MD 20892-9904

Applications must be received not later than June 15, 1994.

Applications received after that date will be returned to the applicant.

The Division of Research Grants will not accept applications in response to this announcement essentially the same as one currently pending initial review at NIH unless the pending application is withdrawn. Submission of identical applications will not be allowed, nor will essentially identical applications be reviewed by different committees.

REVIEW CONSIDERATIONS

General Considerations

All applications will be judged on the basis of their technical and scientific merit and the documented ability of the investigators to meet the objectives of this RFA.

Review Method

Upon receipt, applications will be reviewed by NIH staff for completeness and responsiveness. Incomplete and/or non-responsive applications will be returned to the applicant without further consideration.

Applications may receive a preliminary scientific triage by an NIH initial review group to determine their relative competitiveness. If this triage process is used, the NIH will withdraw from further competition those applications judged to be non-competitive for award and notify the Principal Investigator and institutional official. Those applications that are complete and responsive, and judged to be competitive, will undergo further technical and scientific merit review by an appropriate initial review group convened by the NIH.

Review Criteria

An initial review group convened by the NIH Division of Research Grants will assess the technical and scientific merit of the applications submitted based on the following criteria:

o Scientific and technical merit of the proposed approaches for conducting the project.

o Qualifications and clinical/research training and experience of the Principal Investigator and staff;

o Demonstration that the appropriate AM community linkages exist.

o Availability of resources necessary to perform research assistance activities;

o Appropriateness of the proposed budget;

AWARD CRITERIA

Applications recommended by the NIH Initial Review Group and by the appropriate national advisory council will be considered for award based on (a) scientific and technical merit as determined by peer review, (b) program balance, (c) availability of funds, and (d) geographic representation.

Within the total awards made, the OAM intends to ensure that each of the six program areas is addressed. Thus, if several applications include the same program area, not all of the same duplicate program areas may receive funding so that overall program balance is obtained.

Letter of Intent Receipt Date: May 9, 1994
Application Receipt Date: June 15, 1994
Review by Advisory Council: August/September 1994
Anticipated Award Date: September 30, 1994

INQUIRIES

The opportunity to clarify issues and questions from potential applicants is welcomed by the OAM. Written and telephone inquiries regarding this RFA are encouraged. Inquiries regarding programmatic issues may be directed to:

John Spencer, Ph.D.
Office of Alternative Medicine
National Institutes of Health
6120 Executive Boulevard, Suite 450
Rockville, MD 20892
Telephone: (301) 402-2466
FAX: (301) 402-4741

Inquiries regarding fiscal matters on applications focussing on cancer, may be directed to:

Katharine Schulze
Grants Administration Branch
National Cancer Institute
6120 Executive Boulevard, Room 243
Bethesda, MD 20892
Telephone: (301) 496-7800. 216
FAX: (301) 496-8601

Inquiries regarding fiscal matters on applications focussing on pain, may be directed to:

Diane M. Watson
Grants Management Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 732A
Bethesda, MD 20892
Telephone: (301) 594-9965
FAX: (301) 594-9950

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.213, Research and Training in Alternative Medicine. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal regulations 42 CFR Part 52 and 45 CFR Parts 74 and 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The Public Health Service (PHS) strongly encourages all grant recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

Return to RFAs Index
Return to NIH Guide Main Index